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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,851	05/28/2002	Horst Rapp	HMN 2 0021	8437

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EXAMINER

CHONG, YONG SOO

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/031,851	Applicant(s) RAPP ET AL.	
	Examiner Yong S. Chong	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 6/8/2006. Claim 20 has been cancelled. Claims 1-19 are pending and are examined herein. Applicant's arguments have been fully considered but found not persuasive for reasons of record. All rejections of the last Office Action are maintained and repeated below for Applicant's convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 9-13, and 17 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Wakeman (US Patent 3,317,540) for same reasons of record stated in the Office Action dated November 17, 2004.

Wakeman discloses that tosylchloramide(s) and its known derivatives are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection (see col.1 and col.3 lines 53-56). Wakeman discloses the pharmaceutical compositions of tosylchloramide(s) and their salts in a form, a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion (see col. 2 line 32 to col.3 line 38). Saito et al. discloses that the particular adrenal enzyme inhibitor, trilostane, is useful in the pharmacological treatment of Cushing's syndrome by reducing the steroid production in the patients showing severe hypertension and diabetes mellitus. See title and the English abstract of the Japanese journal article.

Wakeman does not expressly disclose the employment of tosylchloramide(s), in the methods of the particular skin diseases herein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloramide(s) and their salts in methods of the particular skin diseases herein. .

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloramide(s) and their salts in methods of the particular skin diseases herein, because tosylchloramide(s) and their salts are known to be useful in a pharmaceutical composition by topical administration to skin broadly

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and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection according to Wakeman. It is also well-known that the many instant particular skin diseases for examples, psoriasis, aphthae, herpes simplex virus are caused by microorganisms and/or accompanied by microorganisms.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloramide(s) and their salts, the known antiseptics and disinfecting agent would have beneficial therapeutic effects and usefulness in methods of treating instant particular skin diseases for examples, psoriasis, aphthae, herpes simplex virus, by antiseptic action and disinfecting the affected skin area through killing and destroying microorganisms.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandeveld et al (WO 91/07876) for the same reasons of record stated in the Office Action dated November 17, 2004.

Vandeveld et al discloses that tosylchloramide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-8 and claims 1-28). Vandeveld et al. discloses the pharmaceutical compositions of tosylchloramide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts

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of Chloramin T (see Example 1-13 at page 9-20).

Vandeveldt et al. does not expressly disclose the employment of tosylchloramide(s), in methods of the particular skin diseases herein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloramide(s) and their salts in methods of the particular skin diseases herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloramide(s) and their salts in methods of the particular skin diseases herein, because tosylchloramide(s) and their salts are known to be useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus according to Vandeveldt et al.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloramide(s) and their salts, being known in treating skin retrovirus, would have beneficial therapeutic effects and usefulness in methods of treating herpes simplex virus.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harwardt et al (DE 41 37 544) for the same reasons of record stated in the Office Action dated November 17, 2004.

Harwardt et al discloses that tosylchloramide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein

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such as retrovirus (see abstract and page 1-4 and claims 1-7). Harwardt et al. discloses the pharmaceutical compositions of tosylchloramide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-5 at page 3-4).

Harwardt et al. does not expressly disclose the employment of tosylchloramide(s) in methods of the particular skin diseases herein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloramide(s) and their salts in the methods of the particular skin diseases herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloramide(s) and their salts in methods of the particular skin diseases herein, because tosylchloramide(s) and their salts are known to be useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus according to Harwardt et al.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloramide(s) and their salts, being known in treating skin retrovirus, would have beneficial therapeutic effects and usefulness in methods of treating herpes simplex virus.

Response to Argument

Applicant argues that the cited references neither disclose nor suggest the use of tosylchloramide compounds in the treatment of the claimed skin diseases. Applicant cites *Perricone v. Medicis Pharm. Corp.* to support Applicants' position.

Nevertheless, it must be recognized that any judgment on obviousness takes into account knowledge which was generally available and within the level of ordinary skill at the time the claimed invention was made. In this case, as pointed out in the previous Office Action, because tosylchloramide(s) and their salts are known to be useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection according to the cited prior. It is also well-known that the many instant particular skin diseases for examples, psoriasis, aphthae, herpes simplex virus are caused by microorganisms and/or accompanied by microorganisms.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloramide(s) and their salts, the known antiseptics and disinfecting agents would have beneficial therapeutic effects and usefulness in methods of treating instant, particular skin diseases for examples, psoriasis, aphthae, herpes simpfex virus, by antiseptic action and disinfecting the affected skin area through killing and destroying microorganisms.

Moreover, a chemical composition and its properties are inseparable. The

burden is shifted to Applicant to show clear and convincing factual evidence of nonobviousness or unexpected results, i.e., side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For an example, Wakefield et al. disclose topical antiseptics, which are for surface of the body or the skin, antidandruff agents, which are for the hair or scalp, and disinfection agents for the hair (col. 3, lines 53-56). Accordingly, there is ample motivation for the treatment of skin diseases.

Applicant also argues that not all chemical agents useful as a disinfectant would be useful as a pharmaceutical for treating diseases of the skin. This is not persuasive because the standard for obviousness is not absolute success but a reasonable expectation of success. In this case, at least some chemical disinfectants can be used to for treatment of skin diseases so as to give a reasonable expectation of success.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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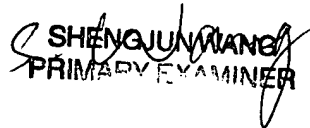
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC


SHENGJUN WANG
PRIMARY EXAMINER